MAY 16 2014

RESEARCH INSTRUMENTS LIMITED

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**510(k) Summary**

**Date prepared**

Wednesday, 07 May 2014

**Submitter**

| | |
|---|---|
| Company Name: | Research Instruments Ltd. |
| Registration Number: | 9617095 |
| Address: | Bickland Industrial Park<br>Falmouth,<br>Cornwall TR11 4TA<br>United Kingdom |
| Telephone: | +44 (0) 1326 372 753 |
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| Contact person: | David Lansdowne |
| Contact Title: | Technical Director |
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**Device Name**

| | |
|---|---|
| Trade Name: | RI Pipettes - Biopsy |
| Common name: | RI Pipettes |
| Classification Name: | Microtools, Assisted Reproduction (21CFR 884.6130, 85 MQH) |
| Classification Panel: | Obstetrics/Gynecology |
| 510(K): | K133257 |

**Predicate Device**

The RI Pipette – Biopsy claim substantial equivalence to two devices which have US market clearance.

**Predicate 1**

| | |
|---|---|
| Trade Name: | RI Pipettes – ICSI Injection, Holding, Assisted Hatching, Denuding |
| Manufacturer: | Research Instruments Ltd |
| Classification Name: | Microtools, Assisted Reproduction |
| 510(K): | K991261 |
| Regulation Number: | 21CFR 844.6130 |
| Product Code: | MQH |

**Predicate 2**

| | |
|---|---|
| Trade Name: | Polar body biopsy micropipet and blastomere biopsy micropipet |
| Manufacturer: | Humagen Fertility Diagnostics, Inc |
| Classification Name: | Microtools, Assisted Reproduction |
| 510(K): | K012811 |
| Regulation Number: | 21CFR 884.6130 |
| Product Code: | MQH |

RESEARCH INSTRUMENTS LIMITED

**Description of the Device**

The Biopsy pipette is part of the RI Pipettes range. Other pipettes available in this range include ICSI Injection, ICSI Holding, and Assisted Hatching pipettes.
Biopsy pipettes are offered in a range

- ID sizes - 14µm, 20µm, 25µm, 30µm, 40µm
- bend angles – 0°, 15°, 20°, 25°, 30°, 35°, 40°, 45°
- tip profiles - flat , non-spiked (bevelled), spiked

All pipettes in this range are manufactured from very fine borosilicate glass, packed individually into a Twista-Pak (primary packaging) and sealed in a medical pouch. They are then batch sterilised by gamma irradiation.

**Summary of Performance Testing**

Each finished batch of pipettes is tested to prove

- non-pyrogenic by Limulus Amoebocyte Lysate (LAL) per AAMI ST72:2002/(R)2010. Testing acceptance: < 20 EU/device
- non-embryotoxic by Mouse Embryo Assay (MEA) Testing acceptance: Pass level: ≥80% blastocyst after 120h

The sterilization process was validated per ISO 11137-1:2006 and ISO 11137-2:2007.

The packaging was validated per ISO 11607-2:2006, ASTM F1980-07, ASTM F1886-09, ASTM F2054-13, and ASTM F1929-12.

Results of real-time aging studies demonstrate the device maintains its specifications for the duration of its shelf life.

**Indications for Use**

Biopsy pipettes are used in assisted reproduction techniques (ART) for the removal of blastomere(s) from embryos or polar bodies from oocytes, which may be done in order to perform preimplantation genetic diagnosis (PGD) on the genetic materials in the biopsied cells(s).

**Technological Characteristics**

RI Pipette – Biopsy claims substantial equivalence to the

1. RI Pipettes range with respect to raw material, manufacturing process, packaging, sealing and irradiation processes, pre-clinical testing and batch release criteria. The only difference between the RI Biopsy pipettes and the other pipettes in the RI range of pipettes is its intended use and tip geometry ie the size and profile of the tip is specific to the 'biopsy' intended use.
2. Humagen Pipettes with regard to raw material, manufacturing and irradiation processes and pre-clinical testing. The intended use is the same and tip geometry is also very similar. Any differences in geometry are the manufacturers' response to perceived user preference and do not affect the safety and effectiveness of the device when used as labelled. The RI Pipettes has a 3 year shelf life where the predicate device has a 2 year shelf life.

These differences do not affect the safety and effectiveness of the device for its intended purpose.

**Conclusion**

The subject device is substantially equivalent to the predicate devices based on intended use, sterilization validation, and bench performance testing (MEA and LAL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2014

Research Instruments Limited
David Lansdowne
Technical Director
Bickland Industrial Park
Falmouth, Cornwall TR114TA
United Kingdom

Re: K133257
Trade/Device Name: RI Pipettes - Biopsy
Regulation Number: 21 CFR§ 884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: II
Product Code: MQH
Dated: April 14, 2014
Received: April 14, 2014

Dear David Lansdowne,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K133257

Device Name
RI Pipettes - Biopsy

Indications for Use *(Describe)*
Biopsy pipettes are used in assisted reproduction techniques (ART) for the removal of blastomere(s) from embryos or polar bodies from oocytes, which may be done in order to perform preimplantation genetic diagnosis (PGD) on the genetic materials in the biopsied cell(s).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
2014.05.16 12:46:44 -04'00'

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